EPA SCIENTIFIC ADVISORY COMMITTEE ON CHEMICALS
CHARGE TO THE PANEL – CYCLIC ALIPHATIC BROMIDES CLUSTER (HBCD)

As amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act on June 22, 2016, the Toxic Substances Control Act (TSCA), requires the U.S. Environmental Protection Agency (EPA) to conduct risk evaluations on existing chemicals. In December of 2016, EPA published a list of the initial ten chemical substances that are the subject of the Agency's chemical risk evaluation process ([HYPERLINK "https://www.federalregister.gov/documents/2016/12/19/2016-30468/designation-of-ten-chemical-substances-for-initial-risk-evaluations-under-the-toxic-substances" \h]), as required by TSCA. HBCD is one of the first ten chemical substances and the second of the ten to undergo a peer review by the Science Advisory Committee on Chemicals (SACC). In response to this requirement, EPA has prepared and published a draft risk evaluation for HBCD which solicited comments from the public and incorporated them as appropriate in the documents considered in this review. HBCD is a clear volatile liquid used primarily as a solvent and is subject to federal and state regulations and reporting requirements.

The draft risk evaluation contains the following components:

- Discussion of chemistry and physical-chemical properties.
- Characterization of uses/sources.
- Environmental fate and transport assessment.
- Environmental release assessment
- Occupational exposure assessment
- Environmental, general population, and consumer exposure assessment
- Environmental hazard assessment
- Human health hazard assessment.
- Risk characterization.
- Risk determination.
- A detailed description of the systematic review process developed by the Office of Pollution Prevention and Toxics to search, screen, and evaluate scientific literature for use in the risk evaluation process.

The focus of this meeting is to conduct the peer review of the Agency's draft risk evaluation of HBCD. At the end of the peer review process, EPA will use the reviewers' comments/recommendations, as well as public comment, to finalize the risk evaluation.

CHARGE QUESTIONS:

1. Content and Organization:

EPA's Final Rule, [HYPERLINK "https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14337.pdf" \h] [HYPERLINK "https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14337.pdf" \h]([HYPERLINK "https://www.federalregister.gov/documents/2017/07/20/2017-14337/procedures-for-chemical-risk-evaluation-under-the-amended-toxic-substances-control-act" \h]) stipulates the process by which EPA is to complete risk evaluations under the Frank R. Lautenberg Chemical Safety for the 21st Century Act, To that end, EPA has completed a draft risk evaluation for HBCD.

As part of this risk evaluation for HBCD, EPA evaluated potential environmental, occupational, consumer, and general population exposures. The evaluation considered reasonably available information, including manufacture, use, and release information, and physical-chemical characteristics. It is important that the information presented in the risk evaluation and accompanying documents are clear and concise and describe the process in a scientifically credible manner.

Please comment on the overall content, organization, and presentation of the draft risk evaluation of HBCD. Please provide suggestions for improving the clarity of the information presented in the documents.

[NOTE: Links to literature flow diagrams, appendices and supplemental files will be provided when they become available]

2. Systematic Review:

The Toxic Substances Control Act (TSCA) requires that EPA use data and/or information in a manner consistent with the "best available science" and that EPA base decisions on the "weight of the scientific evidence". The EPA's Final Rule, [HYPERLINK "https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14337.pdf" \h] [HYPERLINK "https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14337.pdf" \h]([HYPERLINK "https://www.federalregister.gov/documents/2017/07/20/2017-14337/procedures-for-chemical-risk-evaluation-under-the-amended-toxic-substances-control-act" \h]), defines ''best available science'' as science that is reliable and unbiased. This involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data). The Final Rule also defines the "weight of the scientific evidence" as a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.

To meet these scientific standards, EPA applied systematic review approaches and methods to support the draft risk evaluation of HBCD. Information on the approaches and/or methods is described in the draft risk evaluation as well as the following documents:

- [HYPERLINK "https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/application-systematic-review-tsca-risk-evaluations"]
- [HYPERLINK "https://www.epa.gov/sites/production/files/2017-06/documents/14-dioxane_lit_search_strategy_053017.pdf"]
- [HYPERLINK "https://www.epa.gov/sites/production/files/2017-06/documents/14dioxane_comp_bib.pdf"]
- [HYPERLINK "https://www.epa.gov/sites/production/files/2018-06/documents/14-dioxane_problem_formulation_5-31-18.pdf"]

Please comment on the approaches and/or methods used to support and inform the gathering, screening, evaluation, and integration of information used in the draft risk evaluation of HBCD. Please also comment on the clarity of the information as presented related to systematic review and suggest improvements as warranted.

3. Environmental Fate and Transport:

a. HBCD BCF/BAF/BMF/TMF

Measured HBCD BCF values from edible portions of rainbow trout from a reliable study were used to estimate potential human exposure through fish ingestion. The rainbow trout study was selected based on study quality and rainbow trout being an edible species. BAF, BMF, and TMF studies from heavily industrialized areas of China and other non-US countries were also available where these endpoints were evaluated in native species and food webs.

Please comment on the appropriateness of the rainbow trout BCF for use in assessing human exposure via fish ingestion and provide any specific suggestions or recommendations for alternate approaches that could be considered for evaluation.

Please also comment on the potential uses of the BAF/BMF/TMF data from the Chinese and other non-US studies to address human exposure via fish ingestion.

b. Selection of HBCD Environmental Half-Lives for use in Risk Evaluation

A wide range of degradation half-lives have been reported for HBCD in aerobic and anaerobic soil and aerobic and anaerobic sediment and were reviewed for the Risk Evaluation. The selected half-lives were used as input to environmental and human exposure models. The total number of studies was relatively small. Studies from which half-lives were derived were selected based on the relevance of the biodegradation studies to the environmental compartment HBCD is expected to be released or partition to. Thus, studies conducted in water, aerobic soils and sediments were selected.

Please comment on the appropriateness of this approach given the use of the half-lives.

Please provide any specific suggestions or recommendations for alternate approaches that could be considered for evaluation.

4. Environmental Release:

EPA used a combination of estimation methods and approaches to estimate releases for the various

conditions of use (COU). Key environmental release data and data sources that informed the assessment of environmental releases include: release data from the European Communities' HBCD risk assessment reports, TRI data, and Organization of Economic Co-Operation and Development emission scenario documents (OECD ESDs) and Generic Scenarios (GSs).

Please comment on the reasonableness of the methods and approaches used for environmental release estimation and provide any specific suggestions or recommendations for alternative approaches, estimation methods or information that should be considered by the Agency for improving the environment release assessment.

5. *Occupational Exposure*

Workers and occupational non-users may be exposed to HBCD when workers perform activities associated with the conditions of us. These activities include, but are not limited to the following:

- Handling of HBCD during repackaging or during transfer to storage or process vessels
- Machining and shaping of HBCD-containing XPS/EPS foam at industrial sites
- Cutting or breaking HBCD-containing XPS/EPS foam at construction and demolition sites.
- Handling of small transport containers of solder/flux paste containing HBCD.

Approaches for estimating occupational exposure include use of monitoring data and modeling including methods used in EPA's New Chemicals Program. Key data and data sources that informed the occupational exposure assessment include monitoring data reported in the European Communities HBCD Risk Assessment Report, data from the Bureau of Labor Statistics (BLS), Organization of Economic Co-Operation and Development emission scenario documents (OECD ESDs) and Generic Scenarios (GSs).

Please comment on the reasonableness of the estimation methods and approaches used for occupational exposure assessment and provide any specific suggestions or recommendations for alternative approaches, estimation methods or information that should be considered by the Agency for improving the occupational exposure assessment.

6. *Environmental, General Population, and Consumer Exposure*

a. Please comment on EPA's approach to use a tiered method for identify exposure scenarios that have a higher and/lower potential for risk.

b. Please comment on EPA's approach to use receptor-specific exposure factors and activity patterns to estimate doses.

c. Please comment on EPA's approach to prioritize media for estimation of human exposure i.e. dust, soil, outdoor air, dust ingestion, breast milk, and dietary exposure.

d. Please comment on EPA's approach to characterize variability and uncertainty for exposure estimates.

7. *Environmental Hazard*

a. Assessment factors are used to address the differences between the experimental data taking into account the uncertainties in the extrapolation procedure and in the available data set. They cover aspects like interspecies differences, intra-species differences, differences in duration of exposure, issues related to dose-response, quality of the database, etc.

   Currently, OPPT has adopted the assessment factors strategies that are used in the TSCA New Chemicals program. For chronic ecotoxicity, OPPT uses an assessment factor that is commonly used in most ecotoxicity hazard and risk assessments. However, for acute toxicity, the assessment factor varies based on the availability of data and which trophic level that represents the most sensitive species. For fish and daphnia, an assessment factor of "5" is applied and for algae a factor of "4" is used to derive a concentration of concern.

   Please comment on EPA's approach for choosing assessment factors for existing chemicals.

b. We are in the process of implementing the species sensitivity distribution method in order to derive an acute assessment factor for TSCA's workplan chemicals. Please comment on using this approach for HBCD.

c. Please comment on the evaluation of potential HBCD trophic transfer. What other information can be incorporated into the evaluation.

8. Human Health Hazard

a. There are multiple repeat-dose studies that rated "High". The IRIS assessment draft document, which EPA relied heavily on, only selected two studies for dose-response analysis (Ema 2008 and WIL 2001). There is justification for these two studies over the others spread throughout the human health hazard section, but the justification may not be clear. Please comment on whether the selection of only these two studies is well-explained, or whether EPA needs to either better justify or potentially also model the other studies. If modeling of other Medium or High studies is recommended, please provide comment on other high quality studies that might be recommended for further consideration for dose-response for additional critical effects and for acute or chronic exposure scenario consideration.

b. Please comment on the reasonableness of the evaluation of human health hazards. Are there any additional HBCD specific data and/or information that should be considered? Please comment on any other aspect of the human health risk characterization that has not been mentioned above.

9. Risk Characterization / Risk Determination:

a. EPA is currently evaluating integrated risk estimates for the general population in order to account for individuals who live in an area across multiple lifestages? Included scenarios include central tendency (13 year) and higher end (33 year) periods (based on the Exposure Factors Handbook estimates of how long people live in a given area) across a lifetime, integrated across each lifestage as a weighted average. Please comment on EPA's approach.

b. EPA currently considered both reduced pup weight and offspring loss for evaluating risks following acute oral exposures in the general population. Offspring loss was evaluated for risks to all age groups despite children not being of child bearing age. Please comment on EPA's justification in the document.

c. EPA currently considered both reduced pup weight and offspring loss for evaluating risks following acute oral exposures in the general population. Risks for offspring loss were estimated for all age groups despite children not being of child bearing age. Please comment on EPA's justification in the document.

d. EPA does not have any reliable methodology for accounting for the bioaccumulation of HBCD in humans. Our exposure calculations and assumptions are those used for non-bioaccumulative chemicals, so exposure is likely underestimated. We do include a subchronic to chronic 10x UF. Please comment on EPA's approach for accounting for the extra risk from bioaccumulation.

e. Please comment on the reasonableness of the risk characterization. Are there any additional HBCD specific data and/or information that should be considered? Please comment on any other aspect of the risk characterization that has not been mentioned above. T

f. [NOTE: to be developed]

[After consideration of all information identified by the EPA that pertains to HBCD, the EPA concluded that HBCD …….

Please comment on whether the information presented to the panel supports these conclusions outlined in the draft risk evaluation section concerning HBCD. If not, please suggest alternative approaches or information that could be used to develop a risk finding in the context of the requirements of the EPA's Final Rule,[HYPERLINK "https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14337.pdf" \h]([HYPERLINK "https://www.federalregister.gov/documents/2017/07/20/2017-14337/procedures-for-chemical-risk-evaluation-under-the-amended-toxic-substances-control-act" \h][HYPERLINK "https://www.federalregister.gov/documents/2017/07/20/2017-14337/procedures-for-chemical-risk-evaluation-under-the-amended-toxic-substances-control-act" \h]).